IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9058

Bartle, J. May 8, 2013

John R. DeBernardo ("Mr. DeBernardo" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, William A. Esper, D.O., F.A.C.O.I. Based on an echocardiogram dated December 3, 2002, Dr. Esper attested in Part II of claimant's Green Form that Mr. DeBernardo suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40%

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2. (...continued)
Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

to 49%.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $462,103.[4]

In the report of claimant's echocardiogram, Dr. Esper stated that claimant had moderate mitral regurgitation. Dr. Esper, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for Dr. Esper's finding that claimant had moderate mitral regurgitation because his echocardiogram demonstrated only mild mitral regurgitation. Dr. Gradus-Pizlo explained, "The patient has minimal to mild mitral regurgitation[.] [F]rom technical aspects Nyquist is too

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3. Dr. Esper also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue in this claim is claimant's level of mitral regurgitation.

low at 46. There is no ECG tracing on [the echocardiogram], [mitral regurgitant] jet was barely visible, there is no tracing of [mitral regurgitation]."

Based on Dr. Gradus-Pizlo's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. DeBernardo's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant argued that there was a reasonable medical basis for Dr. Esper's representation of moderate mitral regurgitation because his findings were confirmed by an additional echocardiogram that was performed in December, 2005. In addition, Mr. DeBernardo submitted a letter from Jeffrey S. Garrett, M.D., F.A.C.C., wherein he stated:

> Essentially, I agree with Dr. Esper's interpretation. I also would agree with the comments made by the American Home Products interpreting physician that there is evidence of endocardial dropout and that the videotape is of poor technical quality, however, there is no question that this patient does have ... mitral regurgitation, which exceeds 20% left atrial area in the apical four-chamber view.

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. DeBernardo's claim.

Finally, Mr. DeBernardo argues that: (i) the auditing cardiologist's opinion should be disregarded because she did not state her opinion to a reasonable degree of medical certainty, and (ii) the treating physician's opinion is entitled to more weight than the auditing cardiologist's opinion.

Although not required to do so, the Trust forwarded the claim and Mr. DeBernardo's contest materials to Craig Oliner, M.D., another one of its auditing cardiologists, for a second review. Dr. Oliner submitted a declaration in which he confirmed the results of the original audit that there was no reasonable medical basis for Dr. Esper's representation that claimant had moderate mitral regurgitation. Dr. Oliner explained:

> 8. The December 3, 2002 echocardiogram is of very poor technical quality - with horizontal bands significantly distorting the apical views - thus making the evaluation of [mitral regurgitation] particularly difficult, if not impossible. From what I can see, there is no definite [mitral regurgitation] demonstrated on the study.
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> 9. In addition, I observed that the color frame rate (7.0) and the Nyquist setting (46) were both set too low in the apical views and that the color gain setting was consistently set too high. There was also no EKG present, nor was there regurgitant jet area (RJA) measurement performed on the study.
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> 10. Accordingly, for the reasons stated above, there is no reasonable medical basis for a finding of moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Mr. DeBernardo's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Mr. DeBernardo's claim should be paid. On December 19, 2006, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 6785 (Dec. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2007.

In support of this claim, Mr. DeBernardo reasserts the arguments he raised in contest. In addition, he argues the Trust did not properly apply the reasonable medical basis standard, which is not "'whose doctor is right and whose doctor is wrong.'" Mr. DeBernardo contends that the Trust implicitly acknowledged the reasonableness of Dr. Esper's and Dr. Garrett's conclusions because it did not allege a misrepresentation of fact in connection with his claim. For the same reason, Mr. DeBernardo submits that he does not have the burden of proving the representations are true. Mr. DeBernardo also argues that there is a reasonable medical basis for Dr. Esper's and Dr. Garrett's conclusions because they specifically determined the

echocardiogram demonstrated moderate mitral regurgitation while the Trust's auditing cardiologists were equivocal due to the quality of the echocardiogram. Finally, claimant cited two cases where courts, in the workers' compensation context, have determined there was a reasonable basis where medical evidence was susceptible to contrary inferences.

In response, the Trust argues that both auditing cardiologists properly applied the reasonable medical basis standard. The Trust also asserts that Dr. Esper failed to "address or rebut" the findings of the Trust's auditing cardiologists. In addition, the Trust contends that claimant cannot establish a reasonable medical basis for Dr. Esper's representation by referencing an echocardiogram performed three years after the echocardiogram of attestation. Finally, the Trust argues neither Dr. Esper nor Dr. Garrett identify a "sustained, representative mitral regurgitant jet" that meets the 20% RJA/LAA ratio required by the Settlement Agreement.

In December, 2007, Mr. DeBernardo submitted a second completed Green Form signed by his attesting physician, Dr. Esper. Based on an echocardiogram dated December 19, 2005, Dr. Esper attested in Part II of claimant's Green Form that Mr. DeBernardo suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40% to 49%.[6] Based on

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6. Dr. Esper also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $441,349.[7]

In the report of claimant's echocardiogram, Dr. Esper once again stated that claimant had moderate mitral regurgitation. He did not, however, specify a percentage as to claimant's level of mitral regurgitation. As noted previously, under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22.

In July, 2008, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Esper's finding that claimant had moderate mitral regurgitation because the December 19, 2005 echocardiogram demonstrated only mild mitral regurgitation. Dr. Parmar explained that:

> The [echocardiogram] technician did obtain color Doppler signals in the apical 4 chamber view, however, in my opinion, these color Doppler signals are consistent with low

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7. As noted previously, under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of the five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue in this claim as well is claimant's level of mitral regurgitation.

> velocity flow inconsistent with [mitral regurgitation].
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> The jet lasts for about two frames only. Further, I measured the [mitral regurgitant] jet area/LAA ratio at 12%.
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> All of these data points support that the mitral regurgitation is in the mild range.[8]

Based on Dr. Parmar's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. DeBernardo's claim. Pursuant to the Audit Rules, claimant also contested this adverse determination.[9] In contest, Mr. DeBernardo argued that an echocardiogram performed on September 3, 2008 confirmed Dr. Esper's finding of moderate mitral regurgitation. Mr. DeBernardo also submitted a letter from Dr. Garrett, who stated that claimant's December 19, 2005 echocardiogram demonstrated moderate mitral regurgitation "with the regurgitant jet exceeding 20% of the left atrial area." Finally, claimant again argues that (i) the auditing cardiologist's opinion should be disregarded because he did not state his opinion to a reasonable degree of medical certainty, and (ii) the treating physician's opinion is entitled to more weight than the auditing cardiologist's opinion.

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8. Dr. Parmar also reviewed Mr. DeBernardo's December 3, 2002 echocardiogram and concluded that it also demonstrated mild mitral regurgitation. He explained, "Color Doppler patter is visualized which represents low velocity flow and NOT mitral regurgitation." (Emphasis in original.)

9. As this claim was placed into audit after December 1, 2002, there is no dispute that the Audit Rules contained in PTO No. 2807 also apply to this claim.

The Trust then issued a final post-audit determination, again denying Mr. DeBernardo's second claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Mr. DeBernardo's claim should be paid. On February 19, 2009, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 8101 (Feb. 19, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 23, 2009.

In support of this claim, Mr. DeBernardo reasserts the arguments he made in contest. Claimant also argues that the auditing cardiologist and the Trust misapplied the reasonable medical basis standard, which does not require claimant to conclusively disprove Dr. Parmar's conclusion.

In response, the Trust argues that Dr. Parmar properly applied the reasonable medical basis standard. The Trust also asserts the Dr. Garrett's letter fails to "rebut" the findings of Dr. Parmar because it was submitted prior to the audit of this claim and in connection with Mr. DeBernardo's first claim. In addition, the Trust contends that claimant cannot establish a reasonable medical basis for Dr. Esper's representation by

reference to an echocardiogram performed three years after the echocardiogram of attestation.

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and prepare a report for the court. The Show Cause Record and Technical Advisor Report in connection with both claims are now before the court for final determination. See id. Rule 35.

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 3, 2002 and December 19, 2005 echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's findings that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante explained that:

> I reviewed the Claimant's echocardiogram of December 3, 2002.... This was a poor quality videotape with three horizontal lines seen throughout the study. In addition, the study was done below the usual standards of care

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

with significantly increased color gain noted with color artifact outside of the heart. The Nyquist limit was set too low at 46 cm per second at 24 cm of depth. This study was also an incomplete study as the apical two chamber view was not demonstrated. In addition, there was no adequate endocardial definition of the left ventricle in the apical four chamber view. There was no EKG tracing on this study. In spite of these limitations, I was able to accurately evaluate the mitral regurgitant jet in the portion of systole in the apical four chamber view.

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Visually, mild mitral regurgitation appeared to be present in the parasternal long-axis and apical four chamber views. This jet was a centrally located jet that did not reach the back of the left atrium. The left atrium was clearly dilated. I digitized those cardiac cycles in the apical four chamber view in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. I determined that the largest representative RJA in the mid-portion of systole was 3.9 cm2. I determined that the LAA was 28.3 cm2 in the apical four chamber view. Therefore, the largest representative RJA/LAA ratio was 14%. Most of the RJA/LAA ratios were less than 10%. The RJA/LAA ratio never came close to approaching 20%. Low velocity, non-mitral, regurgitant flow was accentuated in this study due to abnormal color gain and a low Nyquist limit. However, I was able to exclude this flow in the calculation of the RJA. There are no sonographer RJA determinations on this study. This study was diagnostic of mild mitral regurgitation.

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I reviewed the CD of Claimant's echocardiogram. The Claimant's name and date of December 19, 2005 were documented on the study.... There were 26 loops/images noted on this study. This study was performed below the usual standards of care. This was

> an incomplete study as the apical two chamber view was not demonstrated on this study. In addition, there was significantly increased color gain during Doppler evaluation of the mitral regurgitant jet in the apical four chamber view. However, the Nyquist limit was appropriately set at 68 cm per second at 19 cm of depth in the parasternal long-axis view and 62 cm per second at a depth of 24 cm in the apical four chamber view. An EKG tracing was appropriately noted on this study. In spite of the above limitations, I was able to accurately evaluate the mitral regurgitant jet in the mid portion of systole during which time there was less color artifact in the apical for chamber view.
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> ....
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> Visually, mild mitral regurgitation was present in the parasternal long-axis and apical four chambers views. This jet was a centrally located jet that reached the mid portion of the left atrium. The left atrium was obviously dilated. The mitral regurgitant jet was delineated in only loops 18 and 22. The mitral regurgitant jet was most impressive in loop 18. I traced and calculated the LAA. I also traced and calculated the RJA in the mid portion of systole in loop 18. I determined that the largest representative RJA was 4.0 cm2. I determined that the LAA was 30.2 cm2 in the apical four chamber view. Therefore, the largest representative RJA/LAA ratio was 13%. The RJA/LAA ratio was less than 10% in loop 22. This study qualified for mild mitral regurgitation. The RJA/LAA ratio never even came close to approaching 20%. There were no sonographer RJA determinations on this study.

The issue presented for resolution of Mr. DeBernardo's claims is whether claimant has met his burden of proving that there is a reasonable medical basis for the attending physician's findings that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable

medical basis for the answers in claimant's Green Forms that are at issue, we must affirm the Trust's final determinations and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim(s) in accordance with the Settlement Agreement. See id. Rule 38(b).

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologists or the Technical Advisor. Specifically, Dr. Gradus-Pizlo, Dr. Oliner, and Dr. Parmar concluded that claimant's December, 2002 echocardiogram was an extremely limited study that did not demonstrate moderate mitral regurgitation. Dr. Parmar concluded that claimant's December, 2005 study also was limited because it contained color Doppler signals consistent with low velocity flow, but determined that the study demonstrated an RJA/LAA ratio of 12%.[11] Finally, Dr. Vigilante reviewed both of these echocardiograms and determined that they demonstrated RJA/LAA ratios of not more than 14% and 13%, respectively.[12] Although Mr. DeBernardo submitted letters from Dr. Esper and Dr. Garrett,

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11. For these reasons as well, we reject claimant's argument that the opinions of the auditing cardiologists should be disregarded because they did not properly apply the reasonable medical basis standard. To the contrary, they each identified particular deficiencies with claimant's echocardiograms.

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

neither of them identified any particular errors in the conclusions of the auditing cardiologists or the Technical Advisor. Mere disagreement with the auditing cardiologists or the Technical Advisor without identifying any specific error by them is insufficient to meet a claimant's burden of proof.

Moreover, we disagree with claimant that Dr. Esper's and Dr. Garrett's letters establish a reasonable medical basis for his claims. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Gradus-Pizlo, Dr. Oliner, and Dr. Vigilante each found that one or more of claimant's echocardiograms used improperly high color gain and/or low Nyquist settings. Further, in evaluating both echocardiograms, Dr. Parmar and Dr. Vigilante each observed that the supposed regurgitant jets included low velocity flow that was not representative of true mitral regurgitation. Claimant's cardiologists did not indicate that they accounted for

these deficiencies in forming their opinions. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation based on either his December 3, 2002 or December 19, 2005 echocardiograms. Therefore, we will affirm the Trust's denial of Mr. DeBernardo's claims for Matrix Benefits.